

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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In re:

MASTER FILE

REZULIN PRODUCTS LIABILITY LITIGATION
(MDL No. 1348)

00 Civ. 2843 (LAK)

This Document Relates to: All Cases
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MEMORANDUM OPINION

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LEWIS A. KAPLAN, *District Judge*.

Among the antecedents of our modern jury trial was wager of law, or compurgation, a form of trial by ordeal. The accused found a number of people and then took a solemn oath that he or she was innocent. The “companions, or ‘compurgators’ as they were called, then swore that the oath which he [or she] had taken was clean. In other words, the court call[ed] upon the accused to produce a specified number of people . . . who [we]re prepared to swear that in their opinion his [or her] oath [wa]s trustworthy. * * * They d[id] not swear to the facts of the case, but merely to their judgment that the accused is a credible person.”¹

A practice reminiscent of wager of law has become fashionable among some well-financed litigants – the engagement of “expert” witnesses whose intended role is more to argue the client’s cause from the witness stand than to bring to the fact-finder specialized knowledge or expertise that would be helpful in resolving the issues of fact presented by the lawsuit. These “experts” thus are loosely analogous to compurgators, also known as oath helpers, in that they lend their credentials and reputations to the party who calls them without bringing much if any relevant knowledge to bear on the facts actually at issue. This case exemplifies the fashion to some extent, as the Plaintiffs’ Executive Committee has engaged a number of “expert” witnesses to perform roles which, in greater or lesser degree, meet this description.

Defendant Warner-Lambert Company and affiliates move *in limine* to exclude certain

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THEODORE F. T. PLUCKNETT, A CONCISE HISTORY OF THE COMMON LAW 115 (5th ed. 1956) (footnote omitted).

proposed testimony of a number of plaintiffs' experts on issues other than silent liver injury, which is the subject of another motion. They object to proposed testimony of plaintiffs' "experts" regarding (1) what constitutes ethical behavior for a company, (2) the motive, intent, and state of mind of actors including Warner-Lambert, Glaxo-Wellcome, U.S. Food and Drug Administration ("FDA") employees, and the authors of scientific articles, (3) Warner-Lambert's alleged suppression of research, (4) foreign regulatory experience with respect to Rezulin [troglitazone] including a "history" of regulatory actions, (5) FDA procedures and regulations and Warner-Lambert's alleged failure to provide adequate information to the FDA about Rezulin, (6) Warner-Lambert's alleged failure adequately to protect patients who participated in the Rezulin clinical trials, (7) what other physicians understood about Rezulin, its benefits and risks, (8) decisions made by physicians who prescribed Rezulin, (9) a duty to warn patients (as well as alleged failure to warn patients); (10) Rezulin's efficacy and its risk-benefit ratio; and (11) one expert's reliance on certain spreadsheets created by a consultant for the defendants.

I. *Legal Framework: Daubert v. Merrell Dow Pharmaceuticals Inc. and Federal Rule of Evidence 702.*

A. *General Background*

The standard governing a district court's determination whether to admit scientific or other expert testimony is familiar. Federal Rule of Evidence 702 provides:

“If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.”

It incorporates principles established in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*,² in which the Supreme Court charged trial courts with a gatekeeping role to “ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable.”³

In *Daubert*, the Supreme Court set forth the procedures a trial court is to follow in ruling on expert testimony. The trial court must determine “whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue.”⁴ The Court explained further that this requires “a preliminary assessment of whether the testimony is scientifically valid and of whether that reasoning or methodology properly can be

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Daubert, 509 U.S. 579 (1993).

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Id. at 589.

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Id. at 592.

applied to the facts in issue” -- in essence, whether it is reliable.⁵ The proponent of expert testimony must demonstrate admissibility by a preponderance of proof.⁶ The *Daubert* Court stressed that the inquiry concerning reliability is “a flexible one” and set forth a list of four nonexclusive factors to consider: (1) whether the expert’s theory “can be (and has been) tested”; (2) whether the theory “has been subjected to peer review and publication;” (3) the “known or potential rate of error”; and (4) whether the theory has ““general acceptance.””⁷

The Court elaborated upon *Daubert* in *Kumho Tire Co. v. Carmichael*,⁸ where it held that *Daubert*’s general gatekeeping obligation “applies not only to testimony based on ‘scientific’ knowledge, but also to testimony based on ‘technical’ and ‘other specialized’ knowledge.”⁹ Ultimately, the objective of *Daubert* is “to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.”¹⁰

In undertaking this inquiry, a district court must focus on the “principles and

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Id. at 592-93.

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Id. at 592 n.10.

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Id. at 593-94.

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526 U.S. 137 (1999).

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Id. at 141.

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Id. at 152.

methodology” employed by the expert, not on the conclusions reached.¹¹ Nevertheless, “nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence which is connected to existing data only by the *ipse dixit* of the expert. A court may conclude that there simply is too great an analytical gap between the data and the opinion proffered.”¹²

In 2000, Rule 702 was amended in light of *Daubert* to require that “(1) the testimony [be] based upon sufficient facts or data, (2) the testimony [be] the product of reliable principles and methods, and (3) the witness [have] applied the principles and methods reliably to the facts of the case.” The Advisory Committee Notes explain that the amendment was intended to affirm *Daubert*’s designation of the trial court as gatekeeper and “provide[] some general standards that the trial court must use to assess the reliability and helpfulness of proffered expert testimony.”¹³ The standards set forth in Rule 702 were not intended to displace the nonexclusive list of factors set forth by the Supreme Court in *Daubert*, however.

One of the fundamental requirements of Rule 702 is that the proposed testimony “assist the trier of fact to understand the evidence or to determine a fact in issue.” This helpfulness requirement is “akin to the relevance requirement of Rule 401, which is applicable to all proffered evidence[,] [but] . . . goes beyond mere relevance . . . because it also requires expert testimony to

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Daubert, 509 U.S. at 594-95.

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General Electric Co. v. Joiner, 522 U.S. 136, 146 (1993).

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Fed. R. Evid. 702 Committee Note (2000).

have a valid connection to the pertinent inquiry.”¹⁴ The *Daubert* Court referred to this as “‘fit,’” noting that “Rule 702’s ‘helpfulness’ standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.”¹⁵ Finally, Rule 702 requires also a finding that the proposed witness be qualified by virtue of specialized knowledge, skill, experience, training, or education.

Recognizing that the application of the foregoing principles, “no matter how flexible, inevitably on occasion will prevent the jury from learning of authentic insights and innovations,” the Supreme Court in *Daubert* nevertheless reasoned that this “is the balance that is struck by Rules of Evidence designed not for the exhaustive search for cosmic understanding but for the particularized resolution of legal disputes.”¹⁶

B. *Specific Considerations.*

Certain principles that are especially pertinent to the task at hand flow from the requirement that expert testimony be “scientific, technical, or other specialized knowledge.” First, the requirement of “knowledge” guards against the admission of subjective or speculative opinions.¹⁷

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4 JACK B. WEINSTEIN & MARGARET A. BERGER, WEINSTEIN’S FEDERAL EVIDENCE § 702.03[1] (Joseph M. McLaughlin ed., 2d ed. 1997).

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Id. at 591; *see also In re Paoli R.R. Yard PCB Litig.*, 916 F.2d 829, 857 (3d Cir. 1990) (helpfulness standard requires more than “bare logical relevance”).

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Daubert, 509 U.S. at 597.

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Daubert, 509 U.S. at 590 (“the word ‘knowledge’ connotes more than subjective belief or unsupported speculation.”)

Second, in requiring that expert testimony be directed to “scientific, technical or specialized” knowledge, Rule 702 ensures that expert witnesses will not testify about “lay matters which a jury is capable of understanding and deciding without the expert’s help.”¹⁸ In other words, experts should not be permitted to “supplant the role of counsel in making argument at trial, and the role of the jury in interpreting the evidence.”¹⁹ Examples of “expert” testimony that courts have excluded on this basis include factual narratives²⁰ and interpretations of conduct or views as to the motivation of parties.²¹

Likewise, in deciding whether the proposed testimony will be helpful to the factfinder, courts in this Circuit analyze the testimony to determine whether it “usurp[s] either the role of the trial judge in instructing the jury as to the applicable law or the role of the jury in applying that law to the facts before it.”²² Thus, although an expert may give an opinion to help the jury decide

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Andrews v. Metro North Commuter Railroad Co., 882 F.2d 705, 708 (2d Cir. 1989) (citations omitted); *accord LinkCo, Inc. v. Fujitsu Ltd.*, No. 00 Civ. 7242, 2002 WL 1585551 (S.D.N.Y. July 16, 2002), at *1; *Taylor v. Evans*, No. 94 Civ. 8425, 1997 WL 154010, at *2 (S.D.N.Y. April 1, 1997).

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Primavera Familienstiftung v. Askin, 130 F. Supp. 2d 450, 527, *amended on reconsideration on other grounds*, 137 F. Supp.2d 438 (S.D.N.Y. 2001).

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See, e.g., Taylor, 1997 WL 154010, at *2.

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See, e.g. Lippe v. Bairnco Corp., 288 B. R. 678, 688 (S.D.N.Y. 2003).

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United States v. Lumpkin, 192 F.3d 280, 290 (2d Cir. 1999) (quoting *United States v. Duncan*, 42 F.3d 97, 101 (2d Cir. 1994)) (quoting *United States v. Bilzerian*, 926 F.2d 1285, 1294 (2d Cir. 1991).

an issue in the case, he or she may not tell the jury what result to reach²³ or communicate “a legal standard – explicit or implicit – to the jury.”²⁴ This principle requires the exclusion of testimony that states a legal conclusion, although factual conclusions on an ultimate issue to be decided by the jury are permissible.²⁵

Against this background, the Court now turns to its analysis of the challenged testimony.

II. Testimony Regarding Ethics.

The reports of two of plaintiffs’ proposed experts indicate that they intend to testify,

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U.S. v. Duncan, 42 F.3d at 100 (“When an expert undertakes to tell the jury what result to reach, this does not *aid* the jury in making a decision, but rather attempts to substitute the expert’s judgment for the jury’s.”) (emphasis in original)

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Hygh v. Jacobs, 961 F.2d 359, 364 (2d Cir. 1992) (trial court improperly admitted testimony defining legal phrase “deadly physical force” in manner inconsistent with applicable definition in New York Penal Law); *United States v. Scop*, 846 F.2d 135, 140, *rev’d in part on reh’g on other grounds*, 856 F.2d 5 (2d Cir. 1988) (excluding expert’s repeated use of statutory and regulatory language indicating guilt); *see also LinkCo, Inc. v. Fujitsu, Ltd.*, No. 00 Civ. 7242, 2002 WL 1585551, (S.D.N.Y. July 16, 2002), at *2 (excluding expert testimony that “it is my expert opinion that [defendant] misappropriated trade secrets that originated at [the plaintiff’s].”)

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Duncan, 423 F. 3d at 101; *Bilzerian*, 926 F.2d at 1294

The rule follows the Advisory Committee’s view that Rules 701, 702 and 403 act as limitations on the use of experts as oath-helpers under Rule 704: “Under Rules 701 and 702, opinions must be helpful to the trier of fact, and Rule 403 provides for exclusion of evidence which wastes time. These provisions afford ample assurances *against the admission of opinions which would merely tell the jury what result to reach*, somewhat in manner of the oath-helpers of an earlier day.” FED. R. EV. 704 advisory committee’s note (West 2003) (emphasis added).

at least in part, that Warner-Lambert, in their opinions, acted in an unethical manner, especially with respect to its presentation of, or reaction to, Rezulin clinical data and the conduct of Rezulin clinical trials. Two other experts gave such testimony in their depositions.²⁶ Defendants seek to preclude all such testimony by plaintiffs' experts. They argue that the opinions are (1) unreliable because

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Dr. Bell stated in his deposition, "The ethical way it should have been presented when it was seen [that] there was an enzyme problem, there usually is not with drugs, was that this should then have been looked at more closely and divided up . . . So I did think this is relevant in this situation that an ethical pharmaceutical company would have presented the data in a different way when, in fact, it was realized there were enzyme elevations." Bell Dep. 146-48. He rendered other similar commentary couched in terms of what constitutes "reasonable and prudent" pharmaceutical conduct in research. *Id.* at 328-32, 340-42. He stated also that he uses the terms "ethical" and "reasonable" interchangeably. *Id.* at 341-42. (This use of the word "ethical" is not to be confused with its use in the phrase "ethical pharmaceutical," which refers to a prescription drug.)

In discussing a document written by another, Dr. Day stated, "I agree with this analysis and believe it to be unethical to conduct studies upon human beings without first fully studying the effects of a drug upon cultured cells and, then, animals." Day Report ¶ 15.

Dr. Kronmal's report expressed views concerning the ethical obligations and duties of pharmaceutical companies, stating "[i]f any indication is present that the investigational drug may be causing serious or potentially adverse events, it is the responsibility of the company to bring this to the attention of the FDA. Anything less than full and complete reporting of any 'signal' that the drug might be dangerous would be unreasonable and unethical behavior that is not standard industry practice." Kronmal Report ¶ 24; *see also id.* ¶¶ 26, 37(c). His deposition testimony is replete with similar judgments. Kronmal Dep. 58-71.

Dr. Furberg's report states that he intends to "comment[] on how the Company adhered to . . . the ethical obligations of practicing physicians, research subjects and regular patients." Furberg Rep. ¶ 8. It states that "[r]esearch sponsors have ethical obligations to the study investigators and to their respective Institutional Review Boards (IRBs) that are similar to their obligations to the FDA" and that "[i]t is my opinion that through a series of deceptive practices, the Company violated accepted standards of clinical trial practice, regulatory guidelines, obligations, trust and codes of ethics. The company directly or indirectly deceived the major parties involved in medical research and patient care . . ." *Id.* at ¶¶ 15, 34. Dr. Furberg said that by "ethical" he means "what is an expected obligation on the part of a responsible sponsor." Furberg Dep. 109-110.

purely speculative; (2) unhelpful to the fact-finder because irrelevant in a case where liability is premised on legal, not ethical, standards, and (3) likely to prejudice and confuse fact-finders concerning the pertinent legal standards. Plaintiffs rejoin that the proffered testimony is reliable and establishes an industry standard that is relevant to the issues in the case.

The opinions of plaintiffs' witnesses, however distinguished these individuals may be as physicians and scientists, concerning the ethical obligations of pharmaceutical companies and whether the defendants' conduct was ethical are inadmissible for the following reasons.

A. *Reliability Under Rule 702 and Daubert.*

Three of plaintiffs' four witnesses — Drs. Day, Bell and Kronmal — have admitted that their opinions concerning purported ethical standards are based on their personal, subjective views.²⁷ These opinions therefore do not meet the core requirement of Rule 702 that expert testimony rest on “knowledge,” a term that “connotes more than subjective belief or unsupported

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At his deposition, Dr. Bell admitted that he was not “an expert on ethics” but that he is entitled to, and holds, a “personal opinion” about “the behavior of pharmaceutical companies.” Bell Dep. 147-48. Plaintiffs' attempt to recast Dr. Bell's challenged testimony as relating to something other than ethics (*viz.* reasonableness) does not alter the effect of Dr. Bell's admission that his opinions in this area — however labeled — are speculative.

Dr. Day's opinion on the ethics of pharmaceutical testing is, by its terms, a personal belief. Day Report ¶ 15 (“*I . . . believe it to be unethical . . .*”) (emphasis supplied).

Dr. Kronmal testified that he knows of no ethical guidelines that apply to the formatting or presentation of data in a New Drug Application and that his view on the ethical obligations of pharmaceutical companies in that regard is based on a personal opinion and his own “subjective views.” Kronmal Dep. 67-70. He testified also that there is “no standard methodology for ethics.” *Id.* at 68. Dr. Kronmal's experience in working on clinical trials and consulting for pharmaceutical companies does not transform his admittedly subjective views on ethical standards into appropriate subjects of expert testimony. *See* Pl. Opp. 7-8.

speculation.”²⁸

Such speculative testimony, contrary to plaintiffs’ argument, cannot serve as the predicate for any purported industry ethical standard.²⁹ Even if expert testimony on the ordinary practices of a profession or trade were appropriate “to enable the jury to evaluate the conduct of the parties against the standards of ordinary practice in the industry,”³⁰ it still must comport with the reliability and helpfulness requirements of Rule 702. At their core, however, the witnesses’ opinions regarding ethical standards for reporting or analyzing clinical trial data or conducting clinical trials articulate nothing save for the principle that research sponsors should be honest.³¹ Even if charitably viewed as a “standard,” the testimony nevertheless is “so vague as to be unhelpful to a fact-finder.”³²

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Daubert, 509 U.S. at 590. *See also Mancuso v. Consol. Edison of New York*, 967 F. Supp. 1437, 1441 (S.D.N.Y. 1997) (expert testimony that is speculative or conjectural is inadmissible) (citations omitted).

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See Grdnich v. Bradlees, 187 F.R.D. 77, 81 (S.D.N.Y. 1999) (excluding expert opinion allegedly based on industry standards as unsupported speculation where only basis for standard were general “common-sense” guidelines.)

To similar effect is *Bush v. Michelin*, cited by the plaintiffs, which stands for the proposition that a court will scrutinize evidence of industry standards to ensure that it is “sufficient to suggest an industry standard.” 963 F. Supp. 1436, 1446 (W. D. Ky. 1996) (reserving decision on admissibility pending court’s review). Similarly unhelpful to the plaintiffs is *Ray v. Wal-Mart Stores, Inc.*, 120 F.3d 882 (8th Cir. 1997), where the reliability of the industry standards evidence was presumed and no claim was raised — as it is here — that the expert’s opinions were purely subjective.

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Marx & Co., Inc. v. Diners’ Club, Inc., 550 F.2d 505, 509-510 (2d Cir. 1977) (citing VII WIGMORE ON EVIDENCE § 1949, at 66 (3d ed. 1940)).

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See note 25.

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Primavera Familienstiftung v. Askin, 130 F. Supp. 2d 450, 529, *amended on reconsideration in part*, 137 F. Supp. 2d 438 (S.D.N.Y. 2001) (Sweet, J.) (excluding as overly vague

Plaintiffs press the notion that “there is no authority proscribing opinions which are personal, a label which can be attached to any expert’s testimony.”³³ The claim, at best, is frivolous word play. Its clear implication is that courts should permit “experts” to tender purely subjective views in the guise of expert opinions. This would border on the absurd.

B. *Relevance Under Rule 702 and Daubert.*

Even assuming that the ethics testimony were based on a reliable foundation, it would not assist the fact-finder in determining any factual dispute in this case. The principal issues here are whether the defendants breached their legal duties to the plaintiffs in the manufacturing, labeling and marketing of Rezulin and, if so, whether any such breaches were proximate causes of injury. While the defendants may be liable in the court of public opinion, or before a divine authority for any ethical lapses, expert opinion as to the ethical character of their actions simply is not relevant to these lawsuits.

Ethics testimony similar to that proposed here was excluded as irrelevant in *Diet*

proposed industry standard testimony that “broker dealers are expected to act with the highest integrity.”)

The fact that Dr. Furberg has three decades of personal experience with clinical trials, Furberg Dep. 28-29, does not render him qualified to opine about purported ethical standards when all that he says is that study sponsors should be honest and that this is “what reasonable people would think,” including his peers in the field of clinical research. *Id.* at 29-30. As Judge Sweet noted in *Primavera*, judges should not be “deceived by the assertions of experts who offer credentials rather than analysis.” *Id.* (citing *Minasian v. Standard Chartered Bank, PLC*, 109 F.2d 1212, 1216 (7th Cir. 1997).

Drugs, a pharmaceutical products liability proceeding analogous in some ways to this MDL.³⁴ There, the court excluded the opinions of a “clinical medical ethics” expert because the testimony was “at best, only marginally relevant to [the manufacturer’s] conduct in the manufacturing and marketing of diet drugs,” and the “pertinent issues in this litigation are the obligations of a pharmaceutical company in testing, surveying and labeling medications.”³⁵ Those same obligations, not what is ethical, are the central issues in this case, and the proffered ethics testimony is “at best, only marginally relevant.”³⁶

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In re Diet Drugs Prod. Liab. Litig., No. MDL 1203, 2001 WL 454586, at *9 (E.D. Pa. Feb. 1, 2001).

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Id. at *9.

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See also Dibella v. Hopkins, No. 01 Civ. 11779, 2002 WL 31427362 (S.D.N.Y. Oct. 30, 2002) (opinions of “business ethics” expert regarding parties’ business dealings inadmissible in commercial dispute; evidence was unhelpful “because the dispute here is not over what is ethical. Rather, the dispute is over what happened.”).

Plaintiffs’ argument that the challenged opinions are relevant to “illuminate the applicable negligence standard” disregards the principle that expert opinions that would encroach on the role of the trial judge in instructing the jury as to the applicable law are inadmissible. *United States v. Lumpkin*, 192 F.3d 280, 289 (quoting *United States v. Duncan*, 42 F.3d 97, 101 (2d Cir. 1994) (quoting *United States v. Bilzerian*, 926 F.2d 1285, 1294 (2d Cir. 1991)).

Plaintiffs’ reliance on *Andrade v. Columbia Med. Center*, 996 F. Supp. 617 (E.D. Tex. 1998), is misguided. In that malpractice case, the court held that expert testimony about the ethical duties of doctors and other health care providers was relevant to the standard of care on the plaintiffs’ claims of ordinary and gross negligence. The *Andrade* decision concluded, without citation, that the ethics testimony would help the jury understand the pertinent standard of care and whether the defendants deviated from it. To the extent that the case turns implicitly on duties that the Hippocratic oath imposes on medical professionals, it is inapplicable to this case, which involves the legal duties of pharmaceutical companies. To the extent that the case is not so limited, the Court declines to follow it. Other precedents relied upon by the plaintiffs are inapposite. *See Ray v. Wal-Mart, supra* (relevance of the expert testimony not challenged); *The Post Office v. Portec, Inc.*, 913 F.2d 802, 807 (10th Cir. 1990), *vacated and remanded on other grounds*, 499 U.S. 915 (1991) (party waived

C. *Federal Rule of Evidence 403.*

Even assuming that the proposed ethics testimony were reliable and marginally relevant under Rule 702, it would be likely unfairly to prejudice and confuse the trier by introducing the “experts’” opinions and rhetoric concerning ethics as alternative and improper grounds for decision on bases other than the pertinent legal standards.³⁷ Accordingly, plaintiffs are precluded from offering any testimony, including that cited in the margin, concerning ethical standards and the application of ethical standards to the alleged conduct of the defendants and others.

III. *Motive, Intent, and State of Mind Testimony*

Several of plaintiffs’ proposed experts have rendered reports articulating, and/or testified in depositions to, opinions concerning the motive, intent and state of mind of Warner-Lambert and others.³⁸ Defendants object that the testimony (1) is unreliable speculation because the

objection to relevance of expert testimony on code of ethical standards for engineers).

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The risk that the legal standard of care and the purported “ethical” standards will be blurred is particularly evident in the cases of Drs. Furberg and Bell, who use the terms “ethical” and “reasonable” interchangeably. *See* Furberg Dep. 109-10; Bell Dep. 146-48, 328-32, 340-42.

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Dr. Furberg addressed Warner-Lambert’s intent and motive in its medical research and patient care, as well as deceptive practices in which Warner-Lambert allegedly engaged. Furberg Rep. ¶¶ 31, 34, 35, 43; Furberg Dep. 158. For example, he said that Warner-Lambert “decided to focus on the incomplete and inaccurate approval data and to minimize the troubling post-approval data.” Furberg Rep. ¶ 43.

Dr. Bell opined on the motive and intent of Warner-Lambert, the FDA, and Glaxo-Wellcome as well as individual witnesses. Bell Report ¶¶ 32, 38, 39-42; Bell Dep. 182-3.

Dr. Gale’s report states: “While it is possible to believe that abnormalities of liver enzymes might slip unremarked through the normal process of drug surveillance, the fact that 20 patients had to be taken off the drug for this reason (one trialist in 125) makes it highly

witnesses lack relevant qualifications, and (2) would invade the province of the jury.³⁹ Plaintiffs rejoin that the witnesses are qualified, and the opinions are helpful under Rule 702 and proper under Rule 704. The Court concludes that the testimony is inadmissible.

First, the opinions of these witnesses on the intent, motives or states of mind of corporations, regulatory agencies and others have no basis in any relevant body of knowledge or

improbable that the company was unaware of this issue prior to marketing. Failing to notice it would constitute negligence; if known, failing to report it and to recommend liver screening would carry more serious implications.” Gale Report ¶ 64. It goes on to say that “[i]t seems clear that Glaxo-Wellcome put the safety of patients before all considerations, and that others involved did not.” *Id.* ¶ 83. He asserted in his deposition that Warner-Lambert was motivated by profit: “If you have a highly profitable product on the market, I think there would be a natural reluctance to withdraw it prematurely. This may have been a factor in the way in which information concerning the safety of this product reached the ears of the regulators and physicians concerned.” Gale Dep. 244-45. He then speculated regarding the motivation of the FDA in making decisions in approving or removing drugs, *id.* at 162, and opined that Glaxo-Wellcome had altruistic motives when it withdrew Rezulin from the UK market.” Gale Report ¶ 83.

Dr. Gale discussed also the intent of authors of a medical article in the *New England Journal of Medicine*, speculating as to why they included a reference to twenty specific patients. “If Dr. Whitcomb found it necessary to write and restate and, indeed, considerably amplify this information 15 months later in the New England Journal, it implies that Dr. Whitcomb did not believe that American physicians were, in general, aware of the advice that had been issued.” Gale Dep. 223. He further stated, “. . . I think one reads any scientific article with some understanding of the intention of the authors.” *Id.*

Dr. Smith accused Warner-Lambert of “suppressing scientific inquiry for the stated purpose of downplaying the hepatotoxic effects of TGZ in the published literature.” Smith Report ¶ 41.

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Defendants argue also that evidence of Warner-Lambert’s profit motive is categorically irrelevant because “profit motive is the foundation of our economic system” and thus cannot serve as a predicate for tort liability. This sweeping argument is frivolous and deserves no further comment. Similarly inapposite is plaintiffs’ lengthy rebuttal, which relies on cases dealing with the relevance of *non-expert* evidence.

expertise.⁴⁰ The *Taylor* court aptly described similar testimony as “musings as to defendants’ motivations [that] would not be admissible if given by any witness -- lay or expert.”⁴¹ Furthermore, plaintiffs’ experts propose improperly to assume the role of advocates for the plaintiffs’ case by arguing as to the intent or motives underlying the conduct of Warner-Lambert or others, a transgression that has resulted in the exclusion of “expert” testimony as to the “real motive” behind

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Dr. Gale admitted that his testimony about Warner-Lambert’s profit motive was an “inference” unrelated to any scientific analysis of the efficacy or benefits as Rezulin. Gale Dep. at 244-245. He admitted also that he had no idea whether Warner-Lambert earned any profits from the sale of Rezulin. *Id.* at 244. He also acknowledged that he was not an expert in corporate intent, just someone who is “able to draw inferences,” *id.* at 245, the same (he also conceded) as non-endocrinologists and lawyers. *Id.* at 245. He admitted too that he has no factual or scientific basis for his views regarding the intent, motive or state of mind of Glaxo-Wellcome, the FDA and the authors of the March 1998 letter to the *NEJM*. *Id.* at 162, 202, 223, 224. In the face of these admissions, it is irrelevant that Dr. Gale may have published a peer-reviewed article in the *Lancet* on the subject of profits driving pharmaceutical companies in general and Rezulin in particular. Regardless of this article, Dr. Gale has admitted that the testimony he proposes to give in *this* case is based on a series of inferences with no basis in fact or scientific method.

Likewise, neither Drs. Smith, Bell, nor Furberg claimed any particular expertise on the intent, motive or state of mind of corporations or regulatory agencies. Thus Dr. Bell cannot provide an expert opinion as to the motives, for example, that underlay Warner-Lambert’s conduct with respect to clinical studies or Glaxo’s motivation for taking Rezulin off the market in Europe. Nor can Dr. Furberg speculate that Warner-Lambert “chose” to allegedly give incomplete information with respect to Rezulin label. And so on.

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Taylor v. Evans, No. 94 Civ. 8425, 1997 WL 154010, at *2 (S.D.N.Y. April 1, 1997) (excluded expert opinions that “Quite frankly, the ECS caseworker removed the Plaintiff’s two children because she did not like her attitude and was unwilling to admit any wrongdoing” and “Mr. Evans was annoyed that Plaintiff did not admit to causing the injuries . . .” and “Mr. Evans did not want to hear Plaintiffs’ story.”). *See also DePaepe v. General Motors Corp.*, 141 F.3d 715, 720 (7th Cir. 1998) (trial court erred by allowing expert to testify as to why General Motors had reduced the amount of padding in its automobile sun visors; expert “lacked any scientific basis for an opinion about the motives of GM’s designers.”)

certain business transactions.⁴²

The testimony is improper also because it describes “lay matters which a jury is capable of understanding and deciding without the expert’s help.”⁴³ Dr. Bell’s proposed testimony illustrates the point. At times he merely repeated facts or opinions stated by other potential witnesses or in documents produced in discovery, as with his reiteration of Dr. Misbin’s view as to what the FDA might have done with different information. Elsewhere, he drew simple inferences from documents produced in discovery, as when he said he “knows for sure” that Glaxo took Rezulin off the market for safety reasons because “the chairman of the company” allegedly wrote this in a letter.⁴⁴ Similar repetitions of facts and speculative inferences about intent appear throughout the challenged testimony.⁴⁵

Inferences about the intent or motive of parties or others lie outside the bounds of expert testimony. As the *Diet Drugs* court stated in excluding testimony that the pharmaceutical defendant’s conduct with respect to labeling was motivated by its desire to increase profits, “[t]he

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Lippe v. Bairnco, 288 B.R. 678, 688 (S.D.N.Y. 2000).

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Andrews v. Metro North Commuter R. Co., 882 F.2d at 708.

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Bell Report ¶ 38; Bell Dep. 182-83.

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Even plaintiffs essentially concede that the testimony consists of “lay matter.” For instance, while denying that Dr. Smith opines about intent or motive — which is untrue, *see* note 38 *supra* — they say that his testimony simply describes “the facts and conditions from which the jury could infer defendant’s motivation in stifling research.” Pl. Opp. 33.

question of intent is a classic jury question and not one for the experts.”⁴⁶

Dr. Gale’s opinion that Warner-Lambert’s conduct with respect to clinical trial data potentially constituted “negligence” or “something more serious”⁴⁷ is excluded for the additional reason that it impermissibly embraces a legal conclusion.⁴⁸ Such testimony “usurp[s] . . . the role of the trial judge in instructing the jury as to the applicable law [and] the role of the jury in applying that law to the facts before it.”⁴⁹

Accordingly, plaintiffs are precluded from offering expert opinion evidence, including that cited in the margin, of the alleged motive, intent or state of mind of defendants or others.

IV. *Testimony about FDA Procedures and Regulations and Disclosure of Facts to the FDA*

Most of plaintiffs’ challenged witnesses have given opinions on FDA procedures, regulations, and standards as well as statements that Warner-Lambert failed adequately to disclose

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In Re Diet Drugs, No. MDL 1203, 2000 WL 876900, at *9 (E. D. Pa. June 20, 2000). *See also In Re Diet Drugs*, No. MDL 1203, 2001 WL 454586, * 2 (E.D. Pa. Feb. 1, 2001) (excluding testimony of expert regarding “what the corporate intent of [defendant] and/or what beliefs of FDA officials were on matters upon which they spoke or acted.”)

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Gale Report ¶ 64.

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See, e.g. United States v. Scop, 846 F. 2d 135, 139-30, *modified*, 856 F. 2d 5 (2d. Cir. 1988) (reversed conviction based on improper expert testimony where witness tracked exact language of securities statutes and regulations which the defendant had allegedly violated and used judicially defined terms such as “manipulation,” “scheme to defraud” and “fraud” in opining on the defendant’s conduct).

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United States v. Lumpkin, 192 F.3d at 289.

material facts about Rezulin to the FDA.⁵⁰ The Court notes

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Dr. Avorn testified that the FDA would have delayed the approval of Rezulin if it had been aware of the potential for, or possibility of, severe hepatotoxicity. Avorn Dep. 311. His report commented that “[i]t further indicates that the manufacturer was in possession of important information on hepatotoxicity that it did not reveal in a complete and timely manner to the Food and Drug Administration or to prescribing physicians.” Avorn Report 1.

Dr. Bell’s report offers extensive commentary on FDA labeling regulations and criticisms of Warner-Lambert’s adherence to those regulations with respect to the Rezulin label. The report is replete also with comments to the effect that Warner-Lambert misled the FDA by providing incomplete or erroneous information. Bell Report ¶¶ 29-51. For example, it states that “[f]ollowing the submission of a ‘4-month Safety Update’ on May 23, 1998, containing erroneous and misleading information with respect to liver toxicity seen in the clinical trials, the FDA approved the Supplemental New Drug Applications for first-line monotherapy and for combination use with sulfonylureas.” *Id.* ¶ 31. *See also id.* ¶¶ 34, 37, 41, 45.

Dr. Bonkovsky expressed the view that, “My impression, from reading the L.A. Times article, is that Warner-Lambert was not entirely forthcoming in reporting the possible hepatotoxicity of Rezulin.” Bell Dep. 95. “And I’ll bet the FDA, in retrospect, wishes they never approved it.” *Id.* 73.

Dr. Furberg’s report and deposition expressed the view that Warner-Lambert submitted erroneous and incomplete safety reports to the FDA and to the FDA Advisory Committee and that this allegedly inadequate disclosure “had consequences for the drug’s approval.” Furberg Report ¶¶ 35, 39; Furberg Dep. 95. Dr. Furberg stated also that “[t]he Company failed to comply with the established FDA guideline for reporting Efficacy and Safety Summary Data and with many of the fundamental principles that form the basis for medical research. It deceived investigators, health care providers, study subjects and regular patients regarding the unacceptable risks of serious liver function abnormalities and damages.” Furberg Report ¶ 46. In addition, he commented on what he called “noteworthy” deposition testimony of Dr. Misbin to the effect that the FDA would not have approved Rezulin monotherapy had it been aware of the true rate of liver injury from the clinical trials. Furberg Rep. ¶ 39.

Dr. Gale offered opinions touching on regulatory matters including comments on FDA requirements for drug studies and aspects of the FDA’s approval process for Rezulin, such as whether Rezulin was placed on a “fast track” approval, or noting that the transcript of a Rezulin Advisory Committee meeting included a comment about liver safety. Gale Rep. ¶¶ 34-36, 56, 57.

Dr. Julie opined that Rezulin probably would not have been “fast-tracked” or approved for

also that all of these challenged opinions to varying degrees recite facts, or agree with opinions, stated in the deposition of Dr. Misbin,⁵¹ including his view that the FDA would not have approved Rezulin monotherapy had it been aware of certain liver injury data from the clinical trials.⁵²

Warner-Lambert seeks to preclude these opinions on the grounds that they are (1) speculative and unreliable because none of the witnesses has expertise in FDA procedures and regulations, and (2) fraud-on-the-FDA evidence which, it claims, is inadmissible under *Buckman Co. v. Plaintiffs' Legal Committee*.⁵³ Plaintiffs rejoin that regulatory expertise is unnecessary because the proffered testimony -- as recharacterized by them -- does not speak to regulatory standards, but merely establishes that Warner-Lambert's disclosures of clinical trial data to the FDA were inadequate and misleading. Plaintiffs claim also that FDA regulations are "minimum" standards. Plaintiffs oppose defendants' *Buckman* argument as an unwarranted extension of that precedent.

first-line therapy had Warner-Lambert presented information to the FDA in a different format. Julie Dep. (7/29/02) 28-30.

Dr. Kronmal discussed FDA standards for the presentation of clinical data and the duties of a pharmaceutical company under those procedures, also offering his view that FDA standards are "minimal." Kronmal Report ¶¶ 23-25.

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Dr. Misbin was an FDA medical officer who participated personally in the review and approval of the Rezulin NDA. He is the only witness that the FDA has made available for a deposition in this case.

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See, e.g., Misbin (12/21/02) Dep. 124-195, 223-224. The references to Dr. Misbin's testimony are explicitly highlighted in plaintiffs' opposition papers. *See, e.g.*, Pl. Opp. 47, 53 (Drs. Furberg and Julie). Approving references to Dr. Misbin appear throughout the experts' deposition transcripts.

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531 U.S. 341 (2001) (state fraud-on-the-FDA claims pre-empted by federal law).

A. *Reliability.*

Despite the plaintiffs' claim to the contrary, portions of the challenged testimony do unequivocally discuss, and evaluate Warner-Lambert's conduct against, FDA standards.⁵⁴ Plaintiffs do not dispute that extensive regulations govern the form and content of clinical data submissions to the FDA⁵⁵ or that the experts here in question disavow any expertise on the subject.⁵⁶ The

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Dr. Bell, for instance, said regarding an FDA regulation that “[i]t is my understanding that proof of causation of these events need not be established in order for a company to add a warning to physicians.” Bell Report ¶ 45. Dr. Bell clearly asserted also that Warner-Lambert did not comply with FDA reporting guidelines. *Id.* ¶ 46. For other examples of opinions that obviously touch on FDA regulations, see note 49.

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See, e.g., 21 C.F.R. §§ 312.47.

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Dr. Avorn is unfamiliar with the FDA-required format for submission of liver data in the Rezulin NDA. Avorn Dep. 142.

Dr. Bell admitted he is “not an expert in U.S. regulatory affairs” and that he did not intend to give expert opinions on the subject. Bell Dep. 22. Despite his disavowal, Dr. Bell did opine on FDA regulations (*see* Bell Report ¶¶ 29-51), but admitted that his views on the subject are “personal,” rather than “scientific,” opinions. Bell. Dep. 97.

Dr. Bonkovsky conceded that he was not “knowledgeable” or an “expert” in the FDA regulatory process. Bonkovsky Dep. (4/13/01) 129-30. This may account for why some of his opinions were based on an “impression” or a “bet.” *See* note 50.

Dr. Gale said that he did not intend to give regulatory testimony and admitted that “the design of studies for the regulatory process” is “beyond [his] area of expertise.” Gale Dep. 152. He admitted also that he lacks expertise on “the details and the minutiae of FDA procedures, what constitutes fast track, accelerated or whatever approvals are details on which I would not care to express a detailed opinion.” *Id.* at 186.

Plaintiffs have offered no pertinent evidence that Drs. Furberg and Julie are qualified to opine on regulatory matters.

Dr. Kronmal admitted that he knows nothing about FDA regulations governing the content and format of NDA submissions — the subject of his opinions. Kronmal Dep. 16, 20, 55, 96, 100. Also, although not dispositive, plaintiffs' counsel himself stated during Dr.

proffered opinions on FDA standards and regulations therefore are inherently unreliable. Further, there is no foundation for the view that FDA regulations are “minimal standards,” for the witnesses cannot characterize — as “minimal” or otherwise — regulations that they do not know or understand in the first place. Plaintiffs’ experts are unqualified also to testify about the *facts* of Warner-Lambert’s disclosures to the FDA because they lack first-hand knowledge.⁵⁷

Accordingly, plaintiffs’ experts that are subject to this aspect of the motion — Drs. Avorn, Bell, Bonkovsky, Gale, Furberg, Julie and Kronmal — are not qualified to render opinions describing or interpreting FDA regulations, or commenting on Warner-Lambert’s adherence to those regulations.

B. *Helpfulness under Rule 702.*

To the extent that the challenged testimony relates, as plaintiffs contend, to the factual accuracy of Warner-Lambert’s clinical data submissions to the FDA, it constitutes lay matter that

Kronmal’s deposition that he is “not an FDA expert.” *Id.* at 104.

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For example, Dr. Kronmal’s deposition is replete with admissions that he lacks first-hand knowledge of the facts underlying defendants’ presentation of NDA data. *See* Kronmal Dep. 61-62, 98, 103-04, 178. Other witnesses gave similar testimony. None, therefore, may opine about the facts or adequacy of the defendants’ presentation of Rezulin clinical data to the FDA or, as with Dr. Bonkovsky, regarding the factual accuracy of information in the Rezulin label.

Plaintiffs’ reliance on *Diet Drugs* is inapposite. There, the court allowed the testimony of a former FDA medical officer on the factual discrepancies between what was known to the defendant drug company and the contents of the drug labeling because he was “*undoubtedly qualified to do so in light of his experience as an FDA officer.*” *See In Re Diet Drugs*, 2000 WL 876900, at *18. (emphasis added). None of the proposed expert witnesses in this case has the same, or analogous, qualifications.

the fact-finder can understand without the assistance of experts, regardless of much experience these witnesses have with clinical trials.⁵⁸ Dr. Avorn's testimony illustrates the point. His view that Warner-Lambert failed to disclose information to the FDA boils down to a contention that Warner-Lambert "buried" certain lab results in an Appendix to the Rezulin NDA.⁵⁹ This opinion does not implicate Dr. Avorn's expertise in pharmacoepidemiology. It is a simple inference drawn from his review of two documents — the primary Rezulin NDA and its Appendix — which, if admissible, plaintiffs' counsel may present directly to the fact-finder while arguing his or her view as to their significance. Expert testimony interpreting Warner-Lambert's conduct in disclosing information to the FDA therefore will not assist the fact-finder in these cases.

C. Federal Rule of Evidence 403.

Numerous portions of the opinions offered by these experts merely recite facts, or endorse opinions, expressed in the deposition of Dr. Misbin. Assuming that Dr. Misbin's testimony is ruled admissible at trial, the challenged opinions are excluded under Rules 702 and 403, as cumulative and certain to waste time.⁶⁰ Plaintiffs' argument that references to Dr. Misbin's testimony serve merely as a "factual basis" for their experts' opinions ignores the fact that plaintiffs'

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See Andrews, 882 F.2d at 708.

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Avorn Dep. 51-55, 142-46.

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The Court expresses no view on the admissibility of Dr. Misbin's testimony because the issue is not before the Court.

experts also repeat Dr. Misbin's *opinions*. Accordingly, the proposed testimony about FDA procedures and regulations and disclosure of facts by Warner-Lambert to the FDA is inadmissible.⁶¹

D. *Dr. Tolman's Testimony.*

Dr. Tolman's report largely to the effect that Warner-Lambert allegedly failed to provide the FDA with all necessary information regarding the risk of liver injury and that the FDA would not have approved Rezulin had it received different information. Defendants object to all of Dr. Tolman's proposed testimony on the ground that he arrived at these conclusions before having supporting data.⁶²

Dispositive here is Dr. Tolman's admission that he "... wrote a lot of the declaration without having the raw information in hand under the assumption that it would be provided to me, so it was sort of coming in around that time, but I wasn't able to reference it when I wrote the declaration . . ."⁶³ Courts applying the principles outlined in *Daubert* have held that an expert may not reach his conclusion first and do the research later.⁶⁴ Because Dr. Tolman wrote his report before

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As the challenged testimony is excluded on the foregoing grounds, the Court does not address the defendants' argument for exclusion under *Buckman*.

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To the extent that Dr. Tolman's testimony relates to disclosures to the FDA or speculation as to what FDA might have done in hypothetical circumstances, it is excluded for the reasons earlier cited with respect to similar testimony of other experts.

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Tolman Dep. 202-03.

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See Wills v. Amerada Hess Corp., No. 98 Civ. 7126, 2002 U.S. Dist. Lexis 1546 at *29 (S.D.N.Y. Jan. 31, 2002); *see also Claar v. Burlington N. R.R. Co.*, 29 F.3d 499, 502-03 (9th Cir. 1994) ("Coming to a firm conclusion first and then doing research to support it is the

having the supporting data, his opinions are not “based upon sufficient facts or data” and do not proceed from “reliable principles and methods,” as required by Rule 702.⁶⁵ Accordingly, all of Mr. Tolman’s testimony is excluded.

V. *History of Rezulin.*

Plaintiffs’ expert Dr. Gale proposes to testify to a narrative reciting selected regulatory events concerning Rezulin, including Advisory Committee meetings, labeling changes, “Dear Doctor” letters, and approval and withdrawal decisions by regulators in the United States and abroad.⁶⁶ Warner-Lambert characterizes the proposed testimony as “nothing more than a repetition of the factual allegations in plaintiffs’ complaint” combined with comments amounting to Dr. Gale’s “spin” on the facts.⁶⁷ Preclusion is sought on the grounds that the testimony (1) is not “knowledge” because it relates to factual matter that does not implicate Dr. Gale’s expertise or first-hand experience, (2) proceeds from a biased and unreliable methodology, and (3) would invade the province of the jury by presenting a narrative that advocates plaintiffs’ version of the facts. Plaintiffs rejoin that Dr. Gale’s narrative merely forms the basis for his opinions and helps to explain his

antithesis of the [scientific] method.”).

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FED. R. EV. 702(1)-(2).

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See Gale Report ¶¶ 55-72, 82-84. *See also* Gale Dep. 186-7.

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Plaintiffs essentially concede that there is nothing technical or scientific about Dr. Gale’s narrative, which they say “is relevant to the testimony of most witnesses, both lay and expert, who will be testifying.” Pl. Opp. 24.

reasoning to the jury, which entitles him to rely on facts of which he lacks personal knowledge.

Dr. Gale’s “history of Rezulin” is merely a “narrative of the case which a juror is equally capable of constructing.”⁶⁸ In Dr. Gale’s own words, the purpose of this testimony is simply to “provid[e] an historical commentary of what happened”⁶⁹ which, in his view, is “important to try and define the staging process” — a term evidently meaning “background.”⁷⁰ Such material, to the extent it is admissible, is properly presented through percipient witnesses and documentary evidence. An expert is not required, for example, to comment that the transcript of the December 11, 1996 Advisory Committee “noted” in response to certain animal data, that “at least in rats we have reason to be concerned about what might happen ultimately in liver, a target tissue.”⁷¹ Likewise, the glosses that Dr. Gale interpolates into his narrative are simple inferences drawn from uncomplicated facts that serve only to buttress plaintiffs’ theory of the case. As plaintiffs’ Rezulin “historian,” therefore, Dr. Gale “does no more than counsel for plaintiff will do in argument, *i.e.*, propound a particular interpretation of [defendant]’s conduct.”⁷² Accordingly, Dr. Gale’s testimony relating to the “history of Rezulin” is inadmissible.

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Taylor, 1997 WL 154010, at *2.

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Gale Dep. 187.

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Id.

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Gale Rep. ¶ 56.

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LinkCo, Inc., 2002 WL 158551, at *2.; *accord GST*, 192 F.R.D. at 111 (“the Court should not shift to [expert] witnesses the responsibility to give conclusory opinions and characterizations of the business conduct portrayed.”)

VI. Foreign Regulatory Experience

Plaintiffs put forth Drs. Avorn, Bonkovsky, Day, Furberg, Gale, and Julie as expert witnesses regarding the actions of foreign regulators and Glaxo-Wellcome with respect to Rezulin.⁷³

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Dr. Avorn commented in his report that “[e]vidence of Rezulin-induced liver damage was substantial enough for the company that marketed it in the United Kingdom, Glaxo-Wellcome, to make a decision to withdraw it from use in that country in November 1997 because of the rapid increase observed in instances of severe liver disease in patients taking the drug, and that company’s concern that it might not be possible either to identify such at-risk patients in advance, or to reverse the progression of fulminant hepatic necrosis once it had begun. Glaxo-Wellcome and Sankyo Pharma withdrew applications to market the drug in 28 countries in November and December 1997, including most of Europe. In October 1998 the Australian regulatory body, the Australian Drug Evaluation Committee, refused to approve Rezulin for use in that country because of concerns about its safety and whether it could possibly be monitored in a way that could prevent fatal hepatic events. A similar position was taken by the comparable review body in New Zealand two months later. The question was also reassessed by the UK Medicines Control Agency in 1998, and in March 1999 the MCA ruled that the available worldwide evidence indicated that the drug could not be used safely.” Avorn Report 3. Dr. Avorn expressed the same opinions in his deposition. Avorn Dep. 158-63.

Dr. Bonkovsky opined that “[e]arly reports of hepatotoxicity in the United States and Japan led the United Kingdom’s Medicines Control Agency to conclude the ‘risk’ of liver disease from troglitazone greatly outweighed any therapeutic ‘benefit’ from the drug. Introduced to the UK’s marketplace in October of 1997, the drug was ‘voluntarily’ removed in December of 1997.” Bonkovsky Report ¶ 8. His report states also that “[i]t is interesting to note that on October 28, 1997 the United Kingdom Medicine’s Control Agency proposed product warnings that Rezulin (troglitazone) ‘is contraindicated in patients with severe hepatic impairment.’” *Id.* at ¶ 27.

Dr. Day discussed the decision of the United Kingdom’s version of the FDA, the Medicines Control Agency (MCA) to remove troglitazone from the market. “Early reports of hepatotoxicity in the United States and Japan led the United Kingdom’s version of the FDA, the Medicines Control Agency (MCA), to decide that the ‘risk’ of liver disease from troglitazone greatly outweighed any therapeutic ‘benefit’ from the drug. After being introduced to the UK’s marketplace in October of 1997 the drug was ‘voluntarily’ removed from the marketplace in December of 1997, a mere 8 weeks or so after its introduction. Subsequent reports and analyses, in my opinion, confirm the validity of this decision to immediately remove troglitazone from the UK marketplace.” Day Report ¶ 36.

Dr. Furberg commented that “[t]he documented rates of liver toxicity led to disapproval of Rezulin by the regulatory agencies in many countries and withdrawal of Rezulin from the

Defendants seek to preclude all evidence, expert or otherwise, on the subject of foreign regulatory actions on the ground that it is irrelevant as a matter of law in a United States product liability litigation governed by United States law. They argue also that, even assuming that the evidence is relevant, it is only marginally so and that its potential for undue prejudice, confusion and waste of time warrants exclusion under Rule 403. With respect to some of the witnesses, including Dr. Avorn, defendants object also on the grounds of qualifications. Plaintiffs rejoin that the testimony is relevant to various issues. They do not address the Rule 403 question.

market in the UK in December of 1997.” Furberg Report ¶ 30. Later, Dr. Furberg stated, “There was no reference made to ... the fact that regulatory agencies in other countries had withdrawn Rezulin from the market due to serious liver damage ...” *Id.* at ¶ 38(C). He said also that “[t]he company’s attitude and practice is in stark contrast to the emphasis on patient safety exemplified in Glaxo-Wellcome’s deliberations in deciding to withdraw Rezulin from the United Kingdom market in December of 1997.” *Id.* at ¶ 43. Dr. Furberg testified about these same foreign regulatory actions at his deposition. Furberg Dep. 196, 207-20.

Dr. Gale extensively discussed the history of Rezulin both in the United States and abroad. Gale Report ¶¶ 55-72. He commented also about foreign regulatory experience stating: “It is extraordinary that, confronted with the identical safety concerns, Glaxo-Wellcome and its American counterparts should have drawn opposite conclusions concerning the advisability of keeping the drug on the market. It seems clear that Glaxo-Wellcome put the safety of patients before all other considerations, and that others involved did not.” *Id.* at 83.

Defendants object also to the opinion at paragraph 56 in Dr. Gale’s report, which they characterize as stating that Rezulin reached concentrations within rat livers 30 times greater than those in the plasma. In fact, that opinion consists merely of Dr. Gale quoting an FDA advisory committee panel that noted that “at least in rats we have reason to be concerned about what might happen ultimately in liver, a target tissue.” *Id.* at ¶ 56. Dr. Gale’s statement regarding animal studies was made in the context of his already-excluded “history of Rezulin” and therefore is inadmissible.

Dr. Julie opined that “[t]o the extent that there were unknowns, the company should have provided that information to physicians much the same as Glaxo did when it withdrew troglitazone from the UK in 1997.” Julie Report ¶ 16. He testified as to the Australian experience with troglitazone at his deposition as well. Julie Dep. (11/22/02) 116-22.

A. *Relevance and Rule 403.*

The Court finds no legal basis upon which now to rule, as urged by Warner-Lambert, that testimony regarding foreign regulatory actions is irrelevant as a matter of law in a United States products liability case governed by American law. The authorities cited by the defendants do not stand for this broad proposition, but rather reflect decisions by various courts to exercise their discretion, in particular cases, to admit or exclude testimony on foreign standards or practices. Any ruling as to the relevancy of otherwise admissible evidence concerning foreign regulatory actions therefore would be premature.

B. *Rule 702.*

Assuming that evidence concerning foreign regulatory actions is relevant and admissible over Rule 403 objections, plaintiffs' experts are not the appropriate vehicles for its introduction. The subject of the testimony is lay matter, similar in nature to Dr. Gale's "history of Rezulin." As review of the witnesses' reports and depositions makes clear, the challenged testimony focuses on a set of non-technical factual allegations — specifically, the actions taken or not taken by foreign regulators or Glaxo-Wellcome with respect to Rezulin — that plaintiffs would use as springboards for arguments about Warner-Lambert's conduct in the United States.⁷⁴ None of it

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The events to which the witnesses consistently refer are Glaxo Wellcome's alleged decision to withdraw Rezulin applications in several countries in late 1997, the alleged decisions of the Australian and New Zealand regulatory agencies not to approve Rezulin, and various alleged actions taken by the British Medicine Control Agency with respect to TGZ.

qualifies as “scientific, technical or other specialized knowledge.”⁷⁵ Accordingly, the proposed testimony of these witnesses is excluded under Rule 702.

VII. Warner-Lambert’s Alleged Suppression of Research

_____ One of the variations on the plaintiffs’ theme that Warner-Lambert concealed information about the alleged toxicity of Rezulin is that the defendants allegedly suppressed the results of in-house scientific studies. Evidently, plaintiffs have designated Dr. Smith to deliver this argument at trial.

Dr. Smith’s report concluded that “it is . . . apparent that Parke-Davis/Warner-Lambert management interfered dramatically with the scientific freedom of the above scientists.”⁷⁶ He accused Warner-Lambert/Parke-Davis also of “suppressing scientific inquiry for the stated purpose of downplaying the hepatotoxic effects of TGZ in the published literature.”⁷⁷

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Plaintiffs argue that Dr. Gale should be allowed to testify as a percipient witness because he was a member of the advisory panel that advised the British Medicines Control Agency (“MCA”) on the risks and benefits of Rezulin and other TZDs, like Actos and Avandia in 1988, when Glaxo-Wellcome applied for the MCA’s permission to reintroduce Rezulin on the British market. Dr. Gale’s testimony, however, makes clear that his involvement was limited to submitting written material to the MCA, and his memory of the events, or even of the advice he gave, is tenuous. Gale Dep. 202-05. Moreover, allowing an expert like Dr. Gale to double as a percipient witness would raise a host of concerns under Rules 702 and 403. *See United States v. Dukagjini*, 326 F.3d 45, 53-56 (2d Cir. 2003) (factual testimony of witness offered in dual role of case agent and expert likely to “attain[] unmerited credibility,” bolster testimony of government fact-witnesses, and “stray from scope of ... expertise.”)

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Smith Report ¶ 41.

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Id.

These opinions are based on Dr. Smith’s review of “in-house documents, memos and emails” — all material produced by the defendants in this case.⁷⁸ For example, he asserts that defendants in 1999 “attempted to block or slow down their own scientists” by “restrict[ing] their access to key databases on computers.”⁷⁹ The sole bases for this assertion are statements of defendants’ in-house scientists that are reproduced in an internal email that purports to discuss changes in employee access to computer servers. All of his proposed testimony relating to the charges of alleged “science-suppression” follows this format. Plaintiffs thus propose to use Dr. Smith to argue, based on other non-technical evidence, from the witness stand. The proposed testimony pertains to “lay matters which a jury is capable of understanding and deciding without the expert’s help.”⁸⁰ It is no more than “arguments and conclusory statements about questions of fact masquerading behind a veneer of technical language.”⁸¹

It is for counsel to make the arguments about the significance of Warner-Lambert’s conduct or omissions with respect to its researchers and not for an expert to testify as to whether the company did or did not do something. Furthermore, Dr. Smith’s statements as to the intent or motives that underlay that same — as yet undetermined — conduct are improper “musings as to the

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Id. at ¶¶ 41-45.

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Id. ¶ 43.

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Andrews, 882 F.2d at 708.

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LinkCo, Inc. v. Fujitsu Ltd., 2002 WL 1585551, at *1.

defendants' motivations."⁸² Finally, an expert who, like Dr. Smith, lacks personal knowledge may "only testify about the underlying facts if he [is] actually bringing to bear his scientific expertise."⁸³ Dr. Smith has no first-hand knowledge of the circumstances underlying his charge of data-suppression but brings no scientific or other technical expertise to bear on his testimony.

Accordingly, all of Dr. Smith's testimony concerning Warner-Lambert's alleged interference with the independence of its in-house scientists or its alleged suppression of scientific research is inadmissible.

VIII. *Warner-Lambert's Alleged Failure Adequately to Protect Patients who Participated in the Rezulin Clinical Trials.*

Two of plaintiffs' proposed experts, Drs. Kronmal and Furberg, have rendered reports expressing the view that Warner-Lambert failed adequately to protect patients in clinical trials of Rezulin.⁸⁴ This testimony is not relevant under Rules 401 and 702 because no plaintiff in this MDL has been identified as a participant in a Rezulin clinical trial. The proposed testimony, even if otherwise admissible, therefore would not "assist the trier" to determine a fact in issue, as required

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See Taylor v. Evans, 1997 WL 154010, at *2. *See also generally* Section III *supra*.

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Pretter v. Metro N. Commuter R.R. Co., No. 00 Civ. 4366, 2002 WL 31163876, (S.D.N.Y. Sept. 30, 2002), at *2.

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Kronmal Report ¶¶ 12-22, 37(a); Furberg Report ¶¶ 34, 42.

by Rule 702. Accordingly, it is inadmissible.⁸⁵

IX. What Other Physicians Understood About Rezulin and its Benefits-Risks.

Two of the plaintiffs' proposed experts, Drs. Gale and Bell, have rendered reports and/or testified in depositions regarding unidentified physicians' understandings of different occurrences, as well as their understanding of the risks and benefits of Rezulin.

Dr. Gale commented repeatedly in his deposition about physicians' understandings of various medications, stating that the significance of a new medication comparing favorably to a placebo "is not always understood" by physicians.⁸⁶ He opined also that physicians do not generally examine a package insert for safety information about a medication, stating that "[t]he insert is – in fact, many physicians, to be quite honest, don't see the inserts, because the insert is something that's only available to the patients, as the doctors do not open the package and take out the insert and read it."⁸⁷ He later expressed the view that "[n]ow, a physician reading a statement saying 'reversible jaundice' thinks this is a harmless condition, self-limiting."⁸⁸

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Dr. Furberg opined that Warner-Lambert's alleged disregard for the safety of participants in the clinical trials violated the guidelines of the International Conference on Harmonization, the Helsinki Declaration of 1964, and other clinical trial guidelines. Dr. Furberg's testimony is not relevant to this litigation for the reasons cited regarding Dr. Kronmal's testimony on the same subject. Accordingly, it too is inadmissible.

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Gale Dep. 154.

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Id. at 225.

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Id. at 252.

Dr. Bell, too, testified about what other physicians understood about the risks and benefits of Rezulin.⁸⁹ He further expressed his view on what was known to the endocrinology community: “This tremendously high mortality rate associated with drug-induced liver disease was not well known and not well appreciated in the endocrinology community.”⁹⁰

Defendants seek to preclude the above-cited testimony on the grounds that Drs. Gale and Bell are not qualified to opine as to what doctors in general think. Plaintiffs concede that

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Bell Report ¶¶ 25-26. Dr. Bell stated, “The need to treat diabetes for the long term, the fact that the complications of diabetes occur only after years of inadequate control and the availability of other agents (with the ability to accomplish glycemic control of Hb A1c) influences the amount of acceptable risk that endocrinologists and others treating diabetes should accept when prescribing new therapies. I have analogized the problem on a simple 1 to 10 ranking scale. If disease and the immediate need for medicines fall on a spectrum from 1 to 10, an invariably fatal disease, like untreated lung cancer is a ‘10’ and if a given drug cured this condition, a risk of death due to a serious adverse side effect would be very tolerable. On the other hand, if acne is a ‘1’ and a given drug caused even one death or serious side effect, that is too much risk, that most people and physicians would not tolerate.” *Id.* at ¶ 25.

Dr. Bell opined also that, “I would consider diabetes to be a ‘4’, or if associated with heart disease, a ‘6’. Given that diabetes can be successfully treated with diet and exercise, the availability of several proven therapies to lower Hb A1c, and the fact that diabetes is a chronic condition whose effects are measured in years, if not decades, the need for a new medication which can lower Hb A1c but that comes with a side effect profile including death and acute fulminate liver failure is not acceptable. This is particularly true in the case of Rezulin where the onset of adverse event usually occurred in the first 4 to 12 months of therapy but the benefits of lower Hb A1c would not take effect until after several years of therapy.” *Id.* at ¶ 26.

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Bell Report ¶ 47.

Dr. Bell devised also a 1-to-10 scale for risk that most physicians would tolerate when prescribing a new therapy, a scale that lacks sufficient scientific methodology to be considered expert testimony. Dr. Bell further stated that he had conferred with fifteen or so colleagues regarding that 1-to-10 scale, conceding that this was obviously not a “scientific methodological approach.” Bell Dep. 245-47. Such conjecture, and a personal scale of risk assessment, do not rise to the level of “knowledge” required by Rule 702.

opinions as to what “doctors in general think” would be inadmissible, but argue that the opinions challenged by the defendants do not fall into this category but rather pertain to the realm of permissible “completeness and accuracy” testimony. The parties’ positions reflect a distinction drawn made by the *Diet Drugs* court.⁹¹

The challenged opinions self-evidently discuss the practices of physicians as to reading labels or package inserts and their understandings of the contents of the Rezulin label. Accordingly, these opinions are excluded under Rule 702 as speculative testimony.⁹² Pursuant to the defendants’ concession, and subject to relevance rulings to be made by the trial courts, these witnesses are not precluded from offering otherwise admissible testimony as to the accuracy of the Rezulin label.⁹³

X. Decisions Made by Prescribing Physicians.

Plaintiffs propose to introduce analogous testimony through Dr. Furberg, to the effect that physicians would not have prescribed Rezulin if they had been provided with more complete

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In Re Diet Drugs, 2000 WL 876900 at *11-12 (E.D. Pa. June 20, 2000) (holding that the court “can easily preclude, from a *Daubert* viewpoint, the rendering of opinions by either of these witnesses as to . . . what doctors in general think, because the witnesses are qualified for that,” but that two particular experts were “fully qualified to opine on the medical facts and science regarding the risks and benefits of the [drugs] in question and to compare that knowledge with what was provided in the text of labeling and warnings on the [drugs] in question.”)

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Id. at *12.

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Defendants allow, for instance, that Dr. Gale may testify about the medical definition of “reversible jaundice.”

information about Rezulin. “By misleading clinicians about the magnitude and seriousness of the liver problem, a large number of patients ended up taking Rezulin instead of safer, more effective and cheaper treatment alternatives. By withholding important safety information about Rezulin from providers, the Company also undermined the physician-patient relationship.”⁹⁴

Defendants seek to preclude this testimony on the grounds that (1) it is speculative because Dr. Furberg lacks expertise in treating diabetics or making risk-benefit assessments for drugs,⁹⁵ and (2) it improperly second-guesses the FDA’s decisions as to the adequacy of the Rezulin label. Plaintiffs attempt to re-characterize Dr. Furberg’s opinions as articulating general principles that physicians require accurate information on labels to make informed decisions and that prescriptions tend to decline when drug labels report adverse events in increasing numbers or frequency. Any physician, plaintiffs argue, is qualified so to opine, so it is irrelevant that Dr. Furberg lacks expertise in diabetology or risk-benefit assessment.

The clear import of Dr. Furberg’s opinions is that physicians would not have prescribed Rezulin if Warner-Lambert had provided different information to physicians. Testimony similar to Dr. Furberg’s was excluded as speculative in *Diet Drugs*. The court there excluded an expert opinion “as to whether [defendants’s] failure to report certain information to the FDA led to

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Furberg Report ¶ 44.

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Dr. Furberg admitted that the treatment of diabetics and the evaluation of a drug’s risk-benefit ratio is “not my field,” Furberg Dep. 63, and admitted that he has no more than a “general sense” as to what drugs were available to treat Type II diabetes when Rezulin was approved. *Id.* at 62.

more suffering and deaths of patients.”⁹⁶ It held that the expert was “not qualified to opine on what decisions would have been made by the numerous physicians who prescribed diet drugs had they been provided with different labeling information. Unlike opining about what physicians in general expect to see on a label, his surmising as to what physicians would do with different information is purely speculative and not based on scientific knowledge.”⁹⁷ Similarly speculative is Dr. Furberg’s testimony as to whether physicians would have prescribed Rezulin if different information about Rezulin had been available. Accordingly, his testimony on this subject is inadmissible.

XI. Duty to Warn Patients

Dr. Furberg’s report included also statements regarding a company’s duty to warn patients. Dr. Furberg first opined that “[s]tudy subjects and regular patients also have the right to be fully informed by drug manufacturers about the drugs being tested or prescribed. To determine whether a treatment selection is acceptable, they need to be aware of all known favorable and unfavorable drug actions.”⁹⁸ In paragraph 45(a) of his report he asserted that by allegedly withholding information Warner-Lambert violated “three basic patient rights issues.” By violating these alleged “three basic patient rights,” Warner-Lambert supposedly violated three corresponding

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In Re Diet Drugs, 2001 WL 454686, at * 18.

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Id.

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Furberg Report ¶ 16 (emphasis in original).

“duties” of (1) full disclosure, (2) not harming others and (3) “distributional justice.”⁹⁹

Warner-Lambert asserts that Dr. Furberg is offering personal opinions that run contrary to controlling law — as embodied in FDA regulations and the learned intermediary doctrine — insofar as they hold that pharmaceutical companies should provide accurate information to patients rather than physicians. Warner-Lambert argues also that Dr. Furberg’s opinions invade the province of judge and jury insofar as they purport to articulate legal standards and then judge Warner-Lambert’s conduct under those standards.

Plaintiffs resist the defendants’ characterization of Dr. Furberg’s opinions, asserting that they concern the “standard of conduct within the medical community” rather than the duties of the pharmaceutical companies to patients, and so do not invade the province of judge or jury. In the alternative, they contend that the opinions do not run contrary to controlling law because the learned intermediary doctrine¹⁰⁰ is inapplicable where, as here, Rezulin was marketed directly to consumers.

Dr. Furberg’s opinions concerning the rights of patients or the duties of pharmaceutical companies are not appropriate expert testimony because they embrace ultimate questions of law outside the province of an expert. As the Second Circuit held in *United States v. Bilzerian*, expert testimony must be circumscribed carefully to ensure that “the expert does not usurp either the role of the trial judge in instructing the jury as to the applicable law and the role of the jury

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The three basic “rights” allegedly are: (1) the right to “self-determination” (a notion akin to informed consent); (2) the right not to be harmed by others (derived from the so-called “principle of non-maleficence”); and (3) the right to not to pay a certain price for a drug when an equally effective, but cheaper, one was available (ostensibly an aspect of the concept of “distributional justice”). Furberg Report ¶ 45.

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See, e.g., *In Re Rezulin Prod. Liab. Litig.*, 133 F. Supp.2d 272, 281-82 (S.D.N.Y. 2001).

in applying that law to the facts before it.”¹⁰¹

Plaintiffs counter that Dr. Furberg’s proposed testimony does not invoke duties “required by law,” but merely sets forth the “standards of conduct within the medical community.” The argument is without merit. Dr. Furberg’s opinions on the “three basic rights” of patients are at best thinly-disguised legal or quasi-legal principles. This is particularly evident in the case of the so-called “principle of self-determination,” which is nothing but a formulation of the doctrine of informed consent.¹⁰² Accordingly, Dr. Furberg’s testimony on the “basic rights of patients” communicates a legal standard and so would encroach on the court’s prerogative to instruct on the law. Dr. Furberg would fare no better if the Court were to view Dr. Furberg’s opinions as articulating a “medical community standard” rather than a legal one: “testimony encompassing an ultimate legal conclusion based upon the facts of the case is not [admissible] *and may not be made*

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926 F.2d 1285, 1294 (2d Cir. 1991).

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According to Dr. Furberg the “right to self-determination requires that a patient be fully informed about potential benefits and risks so that he/she can make an informed decision regarding whether or not to take Rezulin. This was impossible since all relevant safety information was not made available by the Company and misleading and incomplete analysis of the data was given.” Furberg Report ¶ 45(a).

In the circumstances, it is semantic sleight-of-hand for plaintiffs to contend that Dr. Furberg’s opinion about “basic rights” is not a legal standard because the witness does not use the word “legal standards.” (Pl. Opp. 42-43)

Another of Dr. Furberg’s principles is a hybrid of the Hippocratic Oath and the Sixth Commandment: “the principle of non-maleficence signifies that no one should cause harm to others.” *Id.* The Court would no more allow Dr. Furberg to testify here as to the “principle of non-maleficence” than it would permit a priest to testify about the Sixth Commandment under the guise of giving evidence of pharmaceutical industry standards.

so simply because it is presented in terms of industry practice.”¹⁰³

Accordingly, testimony regarding patients’ rights or a duty to warn patients is inadmissible.

XII. *Rezulin’s Efficacy and its Risk-Benefit Ratio.*

Several of plaintiffs’ experts propose to testify regarding Rezulin’s efficacy, risk, and risk-benefit ratio. A précis of the challenged testimony and the Court’s decision regarding each expert follow.

A. *Dr. Bell.*

Dr. Bell opined on the subject of drug-induced liver injury, stating: “I am also aware of evidence suggesting that a Rezulin reaction is worse in patients with pre-existing liver dysfunction.”¹⁰⁴ He suggested also that Rezulin may cause a variety of liver injuries other than those warned about in the label, including cirrhosis.¹⁰⁵ Defendants argue that Dr. Bell is not qualified to offer these opinions because he lacks pertinent expertise.¹⁰⁶ Plaintiffs do not dispute the point but

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Bilzerian, 846 F.2d at 1295 (emphasis added).

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Bell Report ¶ 50.

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Id. at ¶ 33.

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At his deposition Dr. Bell claimed “significant knowledge” about drug-induced liver injury but conceded that he is not an expert on the subject. Bell Dep. 20. He admitted also that he is not board certified in gastroenterology, the discipline that includes the subspecialty of hepatology, has never done a fellowship in hepatology, and never published a

instead deny that the challenged statements are opinions. Rather, they claim, the statements are “undisputed fact[s]” that form the basis for Dr. Bell’s opinions. What opinions those might be, plaintiffs do not say.

This aspect of Dr. Bell’s proposed testimony plainly consists of opinions — opinions that are hotly contested and go to the heart of this litigation. In view of Dr. Bell’s admitted lack of pertinent expertise, the testimony is excluded.

B. *Dr. Bonkovsky.*

Dr. Bonkovsky testified that he agreed with Dr. Gale’s opinion that “there really was never evidence that there was that much more benefit to Rezulin compared with the already available on-the-market treatment.”¹⁰⁷ Defendants object that Dr. Bell lacks the expertise to offer this opinion, citing his admission that he is “not an expert diabetologist or endocrinologist.”¹⁰⁸ Plaintiffs rejoin that a physician’s lack of expertise in the field on which he offers opinions affects its weight, not its admissibility.

As a broad proposition both sides are correct. The Second Circuit has taken a liberal view of the qualification requirements of Rule 702, at least to the extent that a lack of formal training does not necessarily disqualify an expert from testifying if he or she has equivalent relevant

peer-reviewed article on drug-induced liver injury. *Id.* at 18-21.

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Bonkovsky Dep. (9/27/01) 73.

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Id. at 184.

practical experience.¹⁰⁹ On the other hand, *Daubert* nevertheless requires district judges to determine whether the experience of a particular witness warrants placing that individual's view before the trier of fact.

This Court finds Judge Conner's opinion in *Mancuso v. Consolidated Edison*¹¹⁰ instructive. The court there precluded an internist, who worked primarily as a plaintiffs' expert in medical malpractice litigations, from testifying that PCB caused the plaintiff's injuries. The fact that the witness lacked formal training in toxicology or environmental medicine was not dispositive; rather, the Court found that his only relevant experience — exposure, during his medical training, to “many patients [that] had environmental problems” — was insufficient to establish the requisite specialized knowledge regarding the effects of PCBs on “living creatures.”¹¹¹ Likewise, in light of Dr. Bonkovsky's lack of formal training in diabetology or endocrinology, the mere fact that some of his liver patients may have been exposed to Rezulin is insufficient to suggest that he has specialized knowledge on the risks and benefits of Rezulin — a drug that, as a hepatologist, he presumably has had little occasion to prescribe.¹¹²

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Mancuso v. Consolidated Edison of New York, 967 F. Supp.2d 1437 (S.D.N.Y. 1997) (noting, on the basis of *McCulloch v. H.B. Fuller Co.*, 61 F.3d 1038, 1043 (2d Cir. 1995), that the Second Circuit “apparently follows” the Third Circuit's liberal interpretation of the Rule 702 qualification requirement).

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Id.

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Id. at 1043.

C. *Dr. Day.*

Dr. Day testified that he “strongly disagree[s] with Parke-Davis’ delay in ‘voluntarily’ removing troglitazone from the US marketplace, which undoubtedly resulted in many needless cases of hepatotoxicity.”¹¹³ Defendants challenge Dr. Day’s qualifications so to opine.

Dr. Day admitted that he is “not an expert on diabetes in the U.S.”¹¹⁴ He conceded also that a decision whether to keep Rezulin on the market would require an evaluation of the risks versus the benefits, a task for which he is not qualified.¹¹⁵ Indeed plaintiffs concede that “[b]ecause of Dr. Day’s admitted lack of familiarity with Rezulin’s alleged benefits in treating diabetes, Plaintiffs will not offer testimony from him relating to what the Defendants call the *benefit* side of the risk/benefit analysis.”¹¹⁶ But plaintiffs cannot so limit the impact of Dr. Day’s admissions. If he is unqualified to evaluate the benefit side of a risk-benefit analysis for Rezulin then, even assuming that he were qualified to comment on its risks in isolation (he is, after all, a hepatologist with experience in researching drug-induced liver disease),¹¹⁷ he cannot testify about Rezulin’s *relative* risk, as he would have to do in order to address the risk-benefit ratio for Rezulin. Accordingly, Dr. Day’s testimony regarding the efficacy or risk-benefit ratio for Rezulin is excluded.

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Day Report ¶ 36.

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Day (4/12/01) Dep. 14.

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Day (11/26/02) Dep. 254.

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Pl. Opp. 61 (emphasis added).

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Day Report ¶ 8.

D. *Dr. Furberg.*

Dr. Furberg admitted that the efficacy data for Rezulin met FDA standards, under which a diabetes drug is considered effective if it lowers hemoglobin A1C, a measure of blood sugar.¹¹⁸ But he proposes to testify that the FDA should “go beyond” this criterion to require that diabetes drugs should be shown to “reduce macrovascular complications.”¹¹⁹ He admits that this is his “public health viewpoint” and a personal “gold standard” that is not met by any diabetes drug currently on the market.¹²⁰ Defendants object to this testimony as unreliable speculation. Plaintiffs essentially concede the point,¹²¹ but raise a host of insignificant objections which the Court rejects. Dr. Furberg’s testimony regarding efficacy standards to which drug manufacturers ideally should adhere to “is not an ‘expert’ opinion, but rather a personal opinion about what standards [he] believes

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Furberg Report ¶¶ 21, 24; Furberg Dep. 64-65, 78-79.

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Furberg Dep. 69, 73.

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Specifically, Dr. Furberg said, “I take the position that the reason why we are treating patients is to reduce complications of the disease, and I like to see drugs - see whether the drugs reduce these complications. That is the gold standard and I like for these drugs that are to be used by millions of people for decades, I think we should have a standard where it requires all drugs [to] reduce these complications. That’s my public health viewpoint and I’ve taken that position for many, many years and it applies broadly in medicine.” Furberg Dep. 69. *See also* Furberg Report ¶¶ 21, 46; Furberg Dep. 66, 73.

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Plaintiffs’ only effort to oppose it undercuts their position. They assert that “defendants have misread [Furberg’s] testimony,” but their own paraphrase of the testimony confirms that Dr. Furberg proposes to testify about what the FDA should require of manufacturers. *See* Ptf. Opp. 41 (“In fact that testimony is that manufacturers of diabetes drugs should demonstrate that they actually reduce the complications they suffer.”).

should apply to pharmaceutical company conduct.”¹²² It would not help the fact-finder to determine a fact at issue in this litigation. Accordingly, this testimony is excluded.¹²³

E. *Dr. Julie.*

Dr. Julie proposes to testify regarding Rezulin’s efficacy in treating diabetes and its risk-benefit ratio.¹²⁴ Warner-Lambert objects, arguing that Dr. Julie is unqualified because he is not an endocrinologist and lacks expertise in treating diabetes patients.

This does not in itself disqualify Dr. Julie. Defendants do not contest the general assertions in Dr. Julie’s report that he is a board-certified gastroenterologist and has been a practicing physician in gastroenterology and hepatology for over fifteen years.¹²⁵ They simply assert that “more specialized expertise” is required. Regrettably, however, the parties have not addressed the issue of Dr. Julie’s qualifications with respect to the challenged testimony adequately. For example, plaintiffs have not brought to the Court’s attention evidence in the record indicating that Dr. Julie has treated

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See Re Diet Drugs, 2001 WL 454586, at *18.

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The Court does not understand the defendants to be challenging here any testimony by Dr. Furberg to the effect that Rezulin clinical trials did or did not demonstrate efficacy as to particular conditions, *viz.* the prevention of heart attacks, strokes or amputations, which plaintiffs argue would be relevant to rebut the defendants’ contention that Rezulin was proven efficacious in such regard. *See* Pl. Opp. 46. None of the testimony cited by the defendants on this particular motion *in limine* fits this description; rather, it embraces Dr. Furberg’s view critique of Rezulin critical trials as measured against standards that he thinks the FDA ideally should adhere to.

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Julie Dep. (6/27/03) 102-13.

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Julie Report ¶ 1.

diabetic patients with Rezulin, rather than other therapies. Conversely, the defendants do not contest the plaintiffs' allegation that he has treated "numerous diabetic patients."¹²⁶

Accordingly, the defendants' motion *in limine* with respect to Dr. Julie's opinions on the efficacy and risk-benefit of Rezulin is denied without prejudice to renewal.

F. *Dr. Gale.*

Dr. Gale proposes to opine that the risk of Rezulin outweighed its benefits. As to the risk side of the equation he stated in his report that the chance of Rezulin-induced liver failure is 1 in 1000. That number derives from an unpublished December 19, 2000 report by Dr. David Graham, an FDA biostatistician.¹²⁷ Defendants seek to preclude all of Dr. Gale's testimony regarding the risks and benefits of Rezulin on the ground that his testimony about the risks would violate Rules 702 and 703.

1. *Analysis under Rule 703.*

Under Rule 703 a district court may allow an expert to testify based on inadmissible evidence, such as hearsay, if the evidence — here the unpublished Graham report and its conclusion that the risk of Rezulin-induced liver failure is 1:1000 — is "of a type reasonably relied

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Pl. Opp. 53.

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Gale Report ¶ 73.

upon by experts in the particular field.”¹²⁸ *Daubert*’s broad mandate requiring district courts to act as gatekeepers to prevent the admission of untrustworthy expert testimony applies fully to the analysis under Rule 703, and courts have broad discretion in determining whether hearsay evidence is “of a type reasonably relied upon by experts.”¹²⁹ Moreover district courts must make an independent determination that the material in question is sufficiently reliable for experts in the field to rely upon it and are not bound merely “to accept expert testimony based on questionable data simply because other experts use such data in the field.”¹³⁰ The Court, therefore, is not bound by Dr. Gale’s assertion that, in his view, “anyone” would rely on Graham’s report because it was a product of the FDA, an agency that (again, in his view) is widely regarded as the world’s most rigorous and objective source of information on drugs generally and Rezulin in particular.¹³¹ The parties have not brought to the Court’s attention any authorities addressing the reliability of an expert’s reliance on an unpublished study by an FDA employee. Thus the analysis proceeds in the framework of established principles

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FED. R. EV. 703.

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See United States v. Locascio, 6 F.3d 924, 938 (2d Cir. 1993).

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Id.; accord *MTX Communications Corp. v. LDDS/Worldcom, Inc.*, 132 F. Supp.2d 289 (S.D.N.Y. 2001).

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“This report was produced by the FDA, which is widely regarded as the premiere drug-regulating authority in the world. It would be considered by a general observer such as myself as a completely impartial report. In common with the rest of the world, I regard the FDA as being objective and scientific in its statements and evaluations, and therefore I don’t know of anywhere better to go for information . . . [the] report . . . was produced by an agency which now had there or four years of experience with Rezulin, where there were many other people who were fully aware of the data and able to comment on it, so, for this reason, I think it should be considered the best available information.” Gale Dep. 249.

under Rules 702 and 703.

First, defendants correctly note that Dr. Gale viewed the unpublished Graham report as “final” and “definitive.”¹³² And while Dr. Graham labeled the study as a “Final Report,” the same study later was published with the conclusion that the incidence of acute liver failure was 1:4200 — less than one-fourth the rate in the earlier, unpublished report.¹³³ Moreover, plaintiffs do not dispute that under the FDA’s own regulations the unpublished report did not qualify as an official position of the FDA, a fact of which Dr. Gale apparently was unaware.¹³⁴ Thus the December 2000 Graham report itself would appear to be untrustworthy when relied upon, as did Dr. Gale, as a definitive opinion of the FDA.¹³⁵ Moreover, Dr. Gale admitted that he made no effort to ascertain

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Gale Report ¶ 73 (“With respect to liver damage, I have considered as definitive the final report of the FDA”) (citing the Graham December 19, 2000 study); *see also* Gale Dep. 246.

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P. Ex. 16, Graham, *et al.*, “Incidence of Idiopathic Acute Liver Failure and Hospitalized Liver Injury in Patients Treated with Troglitazones,” *American Journal of Gastroenterology*, 98:1, 175-179 (2003).

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“A statement or advice given by an FDA employee orally, or given in writing but not under this section or § 10.90, is an informal communication that represents the best judgment of that employee at that time but does not constitute an advisory opinion, *does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.*” 21 C.F.R. § 10.85(b) (West 2003).

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Graham, *et al.*, “Incidence of Idiopathic Acute Liver Failure and Hospitalized Liver Injury in Patients Treated with Troglitazones,” *American Journal of Gastroenterology*, 2003, 98:1, 175-179.

Plaintiffs’ claim that the “reasonable reliance” requirement of Rule 703 is met because the unpublished Graham report was eventually published and concluded that “troglitazone is a potent hepatotoxin, conferring a substantially increased risk of acute liver injury including [Acute Liver Failure],” is disingenuous in light of the fact that the conclusion reached in that publication diverged substantially from the previous unpublished draft.

whether the unpublished study was, in fact, “definitive” or merely a preliminary draft.¹³⁶ More importantly, however, the Court harbors concerns as to why Dr. Gale would, in a report prepared for this litigation, rely on the 1:1000 ratio expressed in an unpublished study authored by another person, while eschewing his own published, peer-reviewed view that the ratio was in the far lower range of 1:8000 to 1:20,000.¹³⁷ This omission is left unexplained and suggests that Dr. Gale’s reliance on the unpublished Graham report was not based on scientific method but on the expediencies of this particular litigation.¹³⁸ Taken together, all of these factors lead the Court to conclude that Dr. Gale’s reliance on the unpublished Graham report does not comport with Rule 703. To the extent that Dr. Gale’s opinions regarding the risk of Rezulin are based on the 1:1000 ratio found in the unpublished Graham report they therefore are inadmissible.¹³⁹

2. *Analysis under Rule 702.*

Additional aspects of Dr. Gale’s proposed testimony lead to the conclusion that

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See Gale Dep. 249.

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Gale, E. “Lessons from the Glitazones: A Story of Drug Development,” *The Lancet* 357:1870-75, at 1871.

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Plaintiffs’ “argument” that under *Daubert* an opinion may be reliable even if not based on epidemiological data is irrelevant in this context where the issue is Dr. Gale’s failure to consider indisputably relevant and available data.

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Plaintiffs argue that Dr. Gale’s opinion on the risks of Rezulin is not based solely on the Graham report, but on several other sources, including Gale’s pre-litigation peer-reviewed study in the *Lancet*, his review of liver damage in Rezulin clinical trials, the circumstances of Glaxo-Wellcome’s decision to withdraw TGZ in Britain. *See* Gale Dep. 202-205. This argument appears to be unpersuasive at least with respect to Dr. Gale’s ability to opine as to the *incidence* of liver injury in Rezulin users, as by his own admission, the only source for his ratio is the unpublished Graham report. Even Dr. Gale’s own report in this case does not rely on his *Lancet* article as a source for his incidence opinion.

his opinions on the ratio of Rezulin-induced liver failure are unreliable also under Rule 702 and *Daubert*.

First, there is Dr. Gale's admission that he adopted Graham's 1:1000 ratio without considering two epidemiological studies (one published, the other available to him through plaintiffs' counsel) that addressed this very subject but reached drastically different conclusions — viz. a ratio of 1:10,000, which is less than one-fourth that in the Dr. Graham piece.¹⁴⁰ This omission is especially glaring against Dr. Gale's own deposition testimony that in looking at the level of risk of acute liver failure from Rezulin "[a]ll evidence should be taken into account,"¹⁴¹ including epidemiological studies.¹⁴² Although the Selby-Chan study had not been published at the time of Dr. Gale's deposition plaintiffs do not dispute that an abstract and draft were given to plaintiffs' counsel before Dr. Gale's deposition, and that Dr. Selby had been deposed in this case before Dr. Gale. Yet Dr. Gale testified he never had reviewed the abstract or the study and was unaware that Dr. Selby had been deposed this case.¹⁴³ Dr. Gale's selectivity in defining the universe of relevant evidence thus violated his own

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See Gale Dep. 273-74.

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Id. at 279-80. *See* Faich and Mosley, "Troglitazone (Rezulin) and Hepatic Injury," *Journal of Pharmacoepidemiology* (December 2001) (available more than six months before the date of Dr. Gale's report; concluded that risk of acute liver failure from Rezulin at most 1:10,000 and decreased with each year that Rezulin available.); Selby and Chan, "A Cohort of Incidence of Acute Hepatic Failure and Lesser Degrees of Liver Injury in Patients with Diabetes Mellitus," *Hepatology* (October 2001) (quantified the risk of acute liver failure at rate of 1:10,000).

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Id. at 110.

¹⁴³

Gale Dep. 273.

standard of proper methodology that “[a]ll evidence should be taken into account,” which suggests that he does not apply the same rigor in the courtroom that he would apply to his medical endeavors.¹⁴⁴ As the court held in *Lust v. Merrell Dow Pharm., Inc.*,¹⁴⁵ an expert may not “‘pick and chose’ from the scientific landscape and present the Court with what he believes the final picture looks like.”¹⁴⁶ Similarly, in a case cited by the plaintiffs, this Court precluded an expert from testifying in part because he ignored available information that was vital to his opinion.¹⁴⁷

Second, when confronted with the 1:10,000 incidence rates described in the two epidemiological studies that he did not review, Dr. Gale shifted his position, claiming for the first time the “acceptable risk [for Rezulin] is zero”¹⁴⁸ because Rezulin offers “no true benefit.” In a similar vein, he testified that he “challenge[d] the whole concept of what is an acceptable level of risk” for Rezulin because “[wh]ether it’s one in 1,000 or one in 10,000 or even one in 20,000, I will not use that

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Kumho Tire, 526 U.S. at 152.

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89 F.3d 594 (9th Cir. 1996).

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Id. at 596.

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MTX Communic. Corp. v. LDDS/WorldCom, Inc., 132 F. Supp.2d 289, 292-93 (S.D.N.Y. 2001).

While as a general proposition plaintiffs are correct that neither rule 702 nor *Daubert* requires experts to rely on epidemiological data, the dispositive fact here is that Dr. Gale pointedly ignored directly relevant scientific data in violation of his own standards.

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Gale Dep. 369.

drug, because there is no drug worth dying for when it comes to the treatment of diabetes.”¹⁴⁹

The basis for this view, Dr. Gale testified, is that “[Rezulin] is special.”¹⁵⁰ But Dr. Gale acknowledged that death is a side effect of other medications on the market¹⁵¹ and that diabetes medications that he prescribes, such as insulin, metformin and sulfonylureas, also carry serious risks, albeit ones that (to his mind) are not comparable to Rezulin because the benefits of those other drugs, on balance, are higher than those of Rezulin. Moreover, as this Court has written, many of plaintiffs’ other experts have acknowledged that “Rezulin was enormously beneficial to many patients.”¹⁵² Dr. Gale’s view that there is no acceptable risk for Rezulin therefore is so extreme that it appears to be shared by no other expert inside or outside this litigation.

To be sure, *Daubert* explicitly dispensed with the *Frye* general-acceptance standard and held that “some propositions . . . are too particular, too new, or of too limited interest to be published.”¹⁵³ But none of these factors applies to the subject of the incidence rate of Rezulin-induced liver failure, as is evident on this very record which includes relevant publications, including Dr. Gale’s. In the circumstances, the assertion that Rezulin is “special” suggests to the Court that Dr. Gale is not employing in the courtroom the same level of intellectual rigor that characterizes the

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Id. at 312.

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Id. at 270.

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Id. at 279.

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In Re Rezulin Prod. Liab. Litig., 210 F.R.D. 61, 68 (S.D.N.Y. 2002).

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509 U.S. at 593.

practice of an expert in the relevant field, or at the very least this particular expert.¹⁵⁴

3. *Liver Enzyme Testimony.*

Defendants object also to Dr. Gale’s proposed testimony concerning changes in liver enzymes. Relying on an article by Aithal and Day entitled “The Natural History of Histologically Proved Drug Induced Liver Disease,” Dr. Gale opined that the “reversibility of changes in liver enzymes does not necessarily imply that the episode is either concluded or benign” and that “[l]iver inflammation can and often does persist after the drug has been withdrawn.”¹⁵⁵

Defendants argue that this testimony is unreliable because the article Dr. Gale relies upon does not mention Rezulin, Dr. Gale is not aware of any study or article that reaches a conclusion similar to Aithal-Day, and he has not seen any peer-reviewed literature consistent with his opinion.¹⁵⁶ Second, defendants argue that Dr. Gale is unqualified to give this testimony because he is a doctor specializing in the treatment of diabetic patients, but not a hepatologist, and that he has not demonstrated sufficient experience dealing with drug-induced liver injury, to testify about liver

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Kumho Tire, 526 U.S. at 152.

Plaintiffs’ attempt to deny that the “no acceptable risk” opinion conflicts with Dr. Gale’s report — where he consistently opined that the risk-benefit of Rezulin was unacceptable because the risk, expressed in terms of incidence, was 1:1000 — is baseless. Dr. Gale did not hint anywhere in his report that Rezulin was so ineffective that no level of risk would be acceptable.

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Gale Report ¶ 74; Gale Dep. 151-52, 232-33.

¹⁵⁶

See Gale Dep. 258-59.

enzyme changes. Plaintiffs do not oppose, and thus are deemed to admit, the defendants' contentions regarding the unreliability of the challenged testimony. As to Dr. Gale's qualifications, plaintiffs merely assert that defendants' position "carries expert qualification to an illogical extreme" and cite cases outside this Circuit for the general proposition that lack of specialization merely affects the weight, not the admissibility, of expert testimony.

The Court finds that Dr. Gale's opinions on the elevation of liver enzymes is unreliable for the reasons stated by the defendants. Accordingly, his testimony on the subject is inadmissible.

XIII. *Dr. Julie's Opinions on Dr. Watkins's Spreadsheets.*

Dr. Julie opined that Rezulin can cause cirrhosis, basing this view in part on certain spreadsheets created by Dr. Watkins, a hepatology consultant to Warner-Lambert.¹⁵⁷ Defendants challenge this testimony on the ground that it is not "based upon sufficient facts or data" because it is contrary to undisputed evidence in the record — more specifically, Dr. Watkins's own testimony as to the meaning of the spreadsheets. Plaintiffs argue that Dr. Julie's proposed opinions are consistent with deposition testimony that Dr. Watkins's gave regarding a different set of spreadsheets in a separate Rezulin case.

The spreadsheets in question here were prepared by Dr. Watkins to track adverse events associated with Rezulin. In various columns he listed information including the names of the patients, their ages, and the dates of Rezulin use. In a column headed "Comments," Dr. Watkins noted

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Julie Report 3, 8, 11, 17.

information about existing medical conditions or adverse events reported for a particular patient. In some instances he noted the term “cirrhosis.” In another column (or columns), he noted whether Rezulin, in his view, was “possibly” or “probably” the cause of the adverse event — there appear to have been 33 cases with the notation “cirrhosis” of which two were classified as “probably” and nine were classified as “possibly.”¹⁵⁸

At his deposition Dr. Watkins testified as to what he meant when he included the term “cirrhosis” in the “Comments” column — he meant only that “cirrhosis was either reported or some evidence of cirrhosis was present. It was not in any way a statement that Rezulin had caused the cirrhosis.”¹⁵⁹ He testified further that it would be inaccurate to construe his spreadsheets as proof that Rezulin caused cirrhosis.¹⁶⁰ He stated also that the spreadsheets that Dr. Julie relied on were designed as a basis for causation assessments with respect to acute, rather than chronic, liver injuries such as cirrhosis.¹⁶¹ Consequently, he stated, “the fact that cirrhosis appears in my comments section is not related to my assessment . . . [it is merely noted] as a feature of the case.”¹⁶²

Plaintiffs claim that Dr. Watkins’ definition of “probable” with respect to a

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The exhibit submitted to the Court is nearly illegible so it is impossible to determine which column or columns the “probable” and “possible” notations are found in. In any event, there is no dispute between the parties that the document does include such notations.

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Watkins (8/1/02) Dep. 535-36.

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Id. at 535-57.

¹⁶¹

Watkins (8/1/02) Dep. 512-4.

¹⁶²

Id. at 536-7.

different set of spreadsheets, not at issue here, is consistent with Dr. Julie's testimony about the subject spreadsheets. In that context, Dr. Watkins said that the term "probable" meant that "[Rezulin] contributed significantly to the liver event" or that he believed "with a reasonable degree of certainty [that the adverse event was] at least in part related to Troglitazone."¹⁶³

It may well be that there is an issue of fact as to what Dr. Watkins intended when he used the word "cirrhosis" in the spreadsheets relied upon by Dr. Julie. By no stretch of the imagination, however, could one say that Dr. Julie's assumption as to what Dr. Watkins meant be regarded as an appropriate basis upon which to ground expert testimony. He proposes to give an expert opinion based on a guess, not facts.

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Watkins (4/26/02) Dep. 46-47, attached as Exhibit 22 to plaintiffs' Appendix.

XIV. *Conclusion.*

For the foregoing reasons, the defendants' motion *in limine* is granted to the extent set forth above and otherwise denied.

SO ORDERED.

Dated: February 27, 2004

Lewis A. Kaplan
United States District Judge